

Scientific/Technical Advisory Committee World Trade Center Health Program

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Good morning, Advisory Committee members and good morning to members of the public, responders and survivors and other attendees at this inaugural meeting of the World Trade Center Health Program's Scientific/Technical Advisory Committee ("Advisory Committee").

I want to thank each Committee member for agreeing to serve on the Committee. Your time and your advice are greatly appreciated.

The Committee has an important role to play in the World Trade Center Health Program. The James Zadroga 9/11 Health and Compensation Act of 2010 ("Act") specifies three general areas of contributions from the Scientific/Technical Advisory Committee:

(1) The Act *requires* the Administrator to seek advice from the Advisory Committee with regard to determining eligibility criteria for responder and survivor membership in the Program.¹

(2) The Act *requires* the Administrator to seek advice from the Advisory Committee with regard to identifying research needs for the Program.²

(3) The Act also provides that the Administrator *may* consult with the Advisory Committee regarding whether a particular health condition should be added to the List of World Trade Center-Related Health Conditions ("List").³

¹ Section 3311(a)(1)(C) *requires* that before the Administrator makes a determination is made to modify eligibility criteria for a New York City disaster area responder, the Administrator must consult with the Committee. Section 3321 (a)(1)(A)(iii) *requires* that before a determination is made to modify eligibility criteria for a survivor, the Administrator must consult with the Committee. Section 3311(a)(2)(C)(ii) *requires* that before a determination regarding establishing eligibility criteria for responders to the September 11th attacks at the Pentagon and at Shanksville, Pennsylvania, the Administrator must consult with the Committee.

² Section 3341(c), pertaining to research regarding health conditions related to September 11th terrorist attacks, requires that the Administrator carry out this section in consultation with the Advisory Committee

³ Section 3312(a)(6)(A) provides that the Administrator *may* request a recommendation of the Committee whenever the Administrator determines that a proposed rule should be promulgated to add a health condition to the List of WTC-Related Health Conditions. In addition, under Section 3312(a)(6)(B)(i), upon receipt of a petition from an interested party to add a health condition to the List, the Administrator has four options for proceeding—

I would like to provide you brief updates on the three roles of the Advisory Committee:

Eligibility Criteria

No modification of the statutory eligibility criteria for responders or survivors is planned at this time.

Work to determine eligibility criteria for Pentagon and Shanksville responders has begun and is ongoing. Information is being gathered to develop a timeline of onsite response-related activities and exposure information is being accumulated on airborne toxins and other hazards present during the Pentagon and Shanksville responses. I have provided you a brief information sheet on progress to date.

Research

A solicitation for research proposals was announced on April 23, 2011 for the award of research contracts in FY2011 for up to three years with annual budgets of up to \$500,000. Four proposals received funding in July 2011, and four additional proposals received funding in September for the second round of the same announcement (which is now closed).⁴ A brief description of each funded proposal has been provided to you.

A new announcement is currently being planned for FY 2012 funding. The solicitation process for FY 2012 research funds offered by the World Trade Center Health Program will be open to all qualified applicants and will be competitively awarded based on scientific quality criteria. The objective is to support the best science in areas that will most meaningfully contribute to

one of which is to request a recommendation from the Advisory Committee. Section 3312(c) lays out the process the Advisory Committee must follow once the Administrator requests a recommendation.

⁴ The following eight research proposals were awarded for FY2011: (1) Title: *Pulmonary Function Abnormalities, Diastolic Dysfunction and World Trade Center Exposure - Implications for Diagnosis and Treatment*--Organization: Mount Sinai School of Medicine--Principal Investigator: Mary Ann McLaughlin, M.D.; (2) Title: *Burden of Mental-Physical Comorbidity in World Trade Center Responders*--Organization: State University of New York, Stony Brook--Principal Investigators: Evelyn Bromet, Ph.D. and Roman Kotov, Ph.D. from the Department of Psychiatry; Benjamin Luft, M.D. from the Department of Medicine; (3) Title: *Evaluation of Distal Airway Injury Following Exposure to World Trade Center Dust*--Organization: New York University School of Medicine--Principal Investigator: Kenneth I. Berger, M.D.; (4) Title: *Cohort Study of Incident Cancer in the FDNY Responder Population*--Organization: Fire Department of New York--Principal Investigator: David Prezant, M.D.; (5) Title: *Trajectories of Psychological Risk and Resilience in World Trade Center Responders*--Organization: Mount Sinai School of Medicine--Principal Investigator: Adriana Feder, M.D.; (6) Title: *Enhanced Smoking Cessation Intervention for World Trade Center Responders*--Organization: Research Foundation of the State University of New York--Principal Investigator: Evelyn Bromet, Ph.D.; (7) Title: *Cancer Among WTC Responders: Enhanced Surveillance, Exposure, Assessment, and Cancer Specific Risk*--Organization: Mount Sinai School of Medicine--Principal Investigator: Paola Boffetta, M.D.; and (8) Title: *WTC-HEART: Cardiovascular Health Impact and Prediction of Incident (primary and subsequent) Cardiovascular Events Among WTC Responders*--Organization: Research Foundation of CUNY-Queens College--Principal Investigator: Steven Markowitz, M.D..

the scientific priorities for the Program. Suggestions from the Advisory Committee about setting the best scientific priorities for the Program are welcome.

Petitions

With regard to petitions received to date requesting that a health condition be added to the List, the Administrator received a petition to add cancer to the List on September 8, 2011. Pursuant to Section 3312(a)(6)(B)(i) of the Act, the Administrator requested advice from the Advisory Committee on the petition.⁵

Finally, I wanted to speak to you about advice.

As the Committee considers any of the issues brought to it by the Program, it is important to keep in mind that the Scientific/Technical Advisory Committee was established by the Act to provide advice of a *scientific* or *technical* nature to the Administrator.

Unlike the **Responders Steering Committee** or the **Survivors Steering Committee** with their broad representation across the community of interested parties, the Advisory Committee is not established as an advocacy committee. Six members of the Advisory Committee are representatives of the population affected by the terrorist attacks of September 11, 2001, and have been seated on the Committee because of their diverse experiences with the concerns of that population of people rather than due to specific scientific or technical expertise.

⁵ The Administrator's letter sent to the Advisory Committee Chair, Dr. Elizabeth Ward, on October 5, 2011 states: "Under the Act, the STAC has at least 60 days from this request and up to a maximum of 180 days to provide advice. Since the STAC will not be impaneled until November 8, 2011 (nor officially meet until November 9 and 10, 2011), the STAC will have until March 2, 2012 to consider the request, review the available information, and provide their advice." As soon as the Committee membership was named, the Administrator requested the Committee's review of the petition, recognizing that the Advisory Committee cannot initiate any action to review the petition until the Committee members are sworn in on November 8, 2011. The Act requires that the Committee complete the review of the petition within 60 days of the Administrator's request, dated October 5, 2011, which means that the earliest due date is December 4, 2011. At the Administrator's discretion, the Committee may have up to 180 days from the date of the request to submit a recommendation to the Administrator—this moves the final date by which the Committee must submit their recommendation to the Administrator to April 2, 2012. In the October 5, 2011 letter to Dr. Ward, the Administrator specified March 2, 2012 as the date by which the Committee should provide their recommendation. Thus, it is possible for the Committee to ask for an additional 30 days of time to complete their review before the statutory deadline is reached. After the Administrator receives the recommendation from the Committee, the Administrator has an additional 60 days to publish a Federal Register Notice announcing the Administrator's determination on the petition.

The input of the affected population is an important part of any Committee deliberation, as those views ensure that any discussion of science is grounded in the real-world experience of the population affected.

Ultimately, though, articulating a scientific basis for any Advisory Committee recommendation will be of greatest value to the Program.

On behalf of the World Trade Center Health Program, welcome to service on the World Trade Center Health Program's Scientific/Technical Advisory Committee.

Thank you.